IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION	)	MDL NO. 1203
THIS DOCUMENT RELATES TO:	)	
SHEILA BROWN, et al.	)	
v.	)	CIVIL ACTION NO. 99-20593
AMERICAN HOME PRODUCTS CORPORATION	)	2:16 MD 1203

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 8908

Bartle, J. July 10, 2012

Rhonda Leaf ("Ms. Leaf" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,[1] seeks benefits from the AHP Settlement Trust ("Trust").[2] Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").[3]

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1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Mark D. Leaf, Ms. Leaf's spouse, also has submitted a derivative claim for benefits.

3. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the

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To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is to be completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In June 2003, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Azam Ansari, M.D., F.A.C.C. Dr. Ansari is no stranger to this litigation. According to the Trust, he has signed at least 163 Green Forms on behalf of claimants seeking Matrix Benefits. Based on an echocardiogram dated December 13, 2002, Dr. Ansari attested in Part II of Ms. Leaf's Green Form that she suffered from moderate

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presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

mitral regurgitation, an abnormal left atrial dimension, and a reduced ejection fraction in the range of 50% to 60%.[4] Based on such findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of $545,310.[5]

In the report of claimant's echocardiogram, Dr. Ansari observed that "[t]here was moderate mitral regurgitation, which occupied 26-27% of the left atrial surface area." Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22.

In October, 2003, the Trust forwarded the claim for review by Michael F. Salvia, M.D., one of its auditing cardiologists. In audit, Dr. Salvia concluded that there was no reasonable medical basis for Dr. Ansari's finding of moderate

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4. Dr. Ansari also attested that claimant suffered from mild aortic regurgitation and New York Heart Association Functional Class II symptoms. These conditions are not at issue in this claim.

5. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). As the Trust does not contest the attesting physician's finding of an abnormal left atrial dimension, which is one of the conditions needed to qualify for a Level II claim, the only issue is claimant's level of mitral regurgitation.

mitral regurgitation. In support of this conclusion, Dr. Salvia explained that:

> Many of the RJA's measured by the sonographer were low velocity backwash from [mitral valve] closure at the onset of systole. The largest true [mitral regurgitant] jet is about 4cm². The LAA measurement by the sonographer is falsely low as it was obtained in a plane tangential to the maximal [left atrial] diameters. (The low LAA is not concordant with the increased LA diameter.) The true LAA is about 23 cm² which is compatible with the mild [left atrial] enlargement. [T]he RJA/LAA ratio is 17% which fits with the visual quantification of the [mitral regurgitation].

Based on the auditing cardiologist's finding, the Trust issued a post-audit determination denying Ms. Leaf's claim. Pursuant to the Rules for Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.[6] In contest, claimant submitted a supplemental opinion from Dr. Ansari, who reiterated his finding of moderate mitral regurgitation and attached still frames from claimant's December 13, 2002 echocardiogram, which purportedly demonstrated moderate mitral regurgitation. Claimant also argued that the auditing cardiologist mistakenly relied upon her April 4, 1997

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6. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Leaf's claim.

echocardiogram, instead of her December 13, 2002 echocardiogram,[7] and the audit process is flawed because there are additional answer choices to questions on the Report of the Auditing Cardiologist that do not appear on the Green Form.[8]

The Trust then issued a final post-audit determination, again denying Ms. Leaf's claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Ms. Leaf's claim should be paid. On November 10, 2004, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 4135 (Nov. 10, 2004).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special

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7. According to the Report of the Auditing Cardiologist, the auditing cardiologist's findings were based on his review of claimant's December 13, 2002 echocardiogram.

8. Claimant also contended that the auditing cardiologist should be required to declare under penalty of perjury that the information contained in the Report of the Auditing Cardiologist is correct to the best of his or her knowledge. In making this assertion, however, claimant ignores that Dr. Salvia signed an Attestation Form dated October 31, 2003 and a Certification dated October 29, 2004 averring that his findings were true and correct. See generally Audit Rule 7.

Master. The Trust submitted a reply on June 1, 2005, and claimant submitted a sur-reply on June 30, 2005. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor[9] to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor's Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden in proving that there is a reasonable medical basis for the attesting physician's finding that she had moderate mitral regurgitation. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on

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9. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of her claim, Ms. Leaf asserts that the auditing cardiologist "eyeballed" her level of mitral regurgitation, which, according to claimant, is an unacceptable method of measurement. She further alleges that the Report of Auditing Cardiologist contains additional answer choices that are not present on the Green Form.[10] Claimant also maintains that the auditing cardiologist "selectively lowered" her level of mitral regurgitation from moderate to mild, and that the auditing cardiologist's findings lack verifiable evidence. Finally, she contends that the Trust's audit system is flawed and that the auditing cardiologist was disqualified by the court pursuant to PTO No. 4245 (Dec. 15, 2004).[11]

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10. Claimant also submitted a new verified expert opinion from Dr. Ansari and several color still frames. Claimant, however, failed to make the requisite showing of good cause for the submission of this new evidence. See Audit Rule 26. Moreover, claimant's contest materials already contained an expert report and color still frames. Accordingly, the Special Master denied claimant's request to submit new evidence by letter on April 8, 2005.

11. Pursuant to PTO No. 4245, for any claim that was audited by a disqualified auditing cardiologist, the claimant was provided with an opportunity to have his or her claim re-audited by an independent auditing cardiologist. See PTO No. 4245 (Dec. 15, 2004). Despite having the opportunity to select

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The Technical Advisor, Dr. Vigilante, reviewed claimant's echocardiogram and concluded that there was no reasonable medical basis for Dr. Ansari's finding of moderate mitral regurgitation. Specifically, Dr. Vigilante concluded that:

> Mild mitral regurgitation was noted in the apical four chamber and apical two chamber views. This was a small central jet which appeared "bifid" in a few cardiac cycles. The RJA/LAA was less than 15% in all measurable cardiac cycles. Several "stop" frames of color flow doppler were outlined by the sonographer. In addition, the images referred to by Dr. Ansari were reviewed in detail. These stop frame images were not representative of the amount of mitral regurgitation noted on this study. These images were of initial systolic frames containing "backflow". Indeed, these color flow images lasted less than four frames at the beginning of systole and again were not representative of the true degree of mitral regurgitation. Moderate mitral regurgitation was never demonstrated in this study.

In response to the Technical Advisor's Report, claimant argues that Dr. Vigilante ignores the Green Form criteria by excluding backflow from his measurement of mitral regurgitation. According to claimant, as the Green Form definition does not reference backflow, the auditing cardiologist and Technical Advisor are attempting to rewrite the Settlement Agreement's definition of mitral regurgitation. Claimant further avers that

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11. (...continued)
re-audit, claimant declined to do so.

Dr. Vigilante's conclusions were not substantiated by either exhibits or measurements.[12]

After reviewing the entire Show Cause Record, we conclude that claimant's arguments are without merit. First, we disagree with claimant that the auditing cardiologist's finding lacks verifiable evidence and that Dr. Vigilante did not substantiate his findings. To the contrary, the auditing cardiologist identified specific deficiencies with Dr. Ansari's measurements; namely, he included backflow in his measurements, which were obtained in a plane tangential to the maximum left atrium dimensions.[13] Dr. Vigilante also identified specific deficiencies with Dr. Ansari's measurements; namely, he relied upon non-representative regurgitant jets and included backflow in his measurements. On these bases alone, claimant has failed to meet her burden of demonstrating that there is a reasonable medical basis for her claim.[14]

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12. Claimant also contends that Dr. Vigilante lacks the necessary credentials to be a Technical Advisor as set forth in Audit Rule 32. We disagree. We appointed Dr. Vigilante to assist the court in reviewing certain claims in the show cause process after finding that he possessed the requisite skills and expertise. See PTO No. 3212 (Jan. 14, 2002).

13. The auditing cardiologist, therefore, did not selectively downgrade claimant's level of mitral regurgitation from moderate to mild.

14. For these reasons as well, the still frames submitted by claimant are insufficient to establish a reasonable medical basis for her claim.

We also disagree with claimant that "backflow" is considered mitral regurgitation. As we previously explained in PTO No. 2640, conduct "beyond the bounds of medical reason" can include: (1) failing to review multiple loops and still frames; (2) failing to have a Board Certified Cardiologist properly supervise and interpret the echocardiogram; (3) failing to examine the regurgitant jet throughout a portion of systole; (4) over-manipulating echocardiogram settings; (5) setting a low Nyquist limit; (6) characterizing "artifacts," "phantom jets," "backflow" and other low velocity flow as mitral regurgitation; (7) failing to take a claimant's medical history; and (8) overtracing the amount of a claimant's regurgitation. See PTO No. 2640 at 9-13, 15, 21-22, 26 (Nov. 14, 2002). Here, Dr. Salvia and Dr. Vigilante both found that claimant's attesting physician improperly relied on measurements containing "backflow." Such an unacceptable practice by claimant's attesting physician cannot provide a reasonable medical basis for the resulting diagnosis and Green Form answer of moderate mitral regurgitation.

Moreover, claimant's arguments concerning the required method for evaluating a claimant's level of valvular regurgitation are without merit. Although the Settlement Agreement specifies the percentage of regurgitation needed to qualify as having moderate mitral regurgitation, it does not

specify that actual measurements must be made on an echocardiogram. As we explained in PTO No. 2640, "'[e]yeballing' the regurgitant jet to assess severity is well accepted in the world of cardiology." See id. at 15. Claimant essentially requests that we write into the Settlement Agreement a requirement that actual measurements of mitral regurgitation be made to determine if a claimant qualifies for Matrix Benefits. There is no basis for such a revision, and claimant's contention is contrary to the "eyeballing" standards we previously have evaluated and accepted in PTO No. 2640.

Finally, we are not persuaded by claimant's assertion that the Trust's audit system is unfair to claimants. It is claimant's burden in the show cause process to show why she is entitled to Matrix Benefits. See Audit Rule 24. The audit and show cause process, as approved by this court, provide claimant with notice and an opportunity to present her evidence in support of her claim.[15] Claimant has not provided any evidence that the audit of her claim was not done in an objective manner. We, therefore, reject claimant's challenge to the audit process.

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15. We also reject claimant's argument that there are inconsistencies between the possible answers on the Green Form and the Auditor's Report. Although the Auditor's Report includes additional selections for the level of mitral regurgitation and ejection fraction, these choices have no bearing on whether a claim is eligible for Matrix Benefits.

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for finding that she had moderate mitral regurgitation. Therefore, we will affirm the Trust's denial of Ms. Leaf's claim for Matrix Benefits and the related derivative claim submitted by her spouse.